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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,113

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Preben Lexow

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1894

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7590

09/17/2009

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,113	Applicant(s) LEXOW ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' response to the office action field on May 19, 2009 has been considered and acknowledged.
2. The amendment filed on 5/19/09 has been considered and acknowledged. It is noted that the amended claim 13 incorporated new limitations that are not underlined.

Status of the Application

3. Claims 8-16 are pending under examination. Claims 1-7 were cancelled and new claim 16 is added. All arguments and amendment have been fully considered and deemed persuasive in part for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The action is made FINAL.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9, 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (WO 00/39333).

Jones et al. teach a method of claim 13, Jones et al. teach a method for determining the sequence of a target polynucleotide comprising

i) treating a sample of a double stranded target polynucleotide to create overhangs at each end having defined number of bases in each overhang (see page 33, line 17-35, page 54, line 13-22);

ii) dividing sample and contacting each sample with a signal sequence and a double stranded adapter sequence and ligating said sequences (see page 54, line 19-31);

iii) carrying out polymerase chain reaction using primers that hybridize to the ends of the polynucleotide, optionally repeating the steps (see page 54, line 32-37);

iv) identifying the presence of the signal sequences on the amplified products, in which order, and determining the sequence of the target polynucleotide (see page 55, line 1-6, page 36, line 24-37).

With regard to claim 8-9, Jones et al. teach that the restriction enzyme recognition sequence is specific for a class IIs enzyme that includes SfaN1 (see page 66, line 34).

With regard to claim 11, Jones et al. teach that the adapter is immobilized on a solid support (see page 42, line 4-14).

With regard to the claim 12, Jones et al. teach that the amplification is carried out by using polymerase chain reaction using adapter sequence as primers (see page 38, line 35-37, page 19, line 1-18).

With regard to claims 14-15, Jones et al. teach that the overhang comprises at least 3 or 4 bases (see page 38, line 23-34).

With regard to claim 16, Jones et al. teach that the signal sequence comprises all combinations of (see page 34, line 5-37).

Accordingly the instant claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (WO 00/39333) in view of Sorge et al. (US 6,017,701).

Jones et al teach a method for identifying specific characteristics of a target polynucleotide in a sample as discussed above in section 5. However Jones et al. did not teach use of methyl-dCTP.

Sorge et al. teach a method for amplification of a nucleic acid using 5-methyl-dCTP nucleotides (See col. 8, line 46-64, col.19, line 27-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method for determining the characteristics of a target polynucleotide as taught by Jones et al. with a methyl-dCTP as taught by Sorge et al. to achieve an expected advantage of developing an improved and efficient method for characterizing the target nucleic acid. An ordinary practitioner would have been motivated to combine the references because one skilled in the art would have a reasonable expectation of success that the combination would result in a sensitive and enhanced method for detecting specific target nucleic acid sequences because Sorge et al. explicitly taught the efficiency of the methyl-dCTP in increasing the melting temperature of the amplification products and provide efficient specific PCR amplification by reducing the non-specific amplification stability (see col. 19, line 37-52) and such modification of the method is considered obvious over the cited prior art.

Response to arguments:

6. Applicants' arguments and the amendment with regard to the informalities and objection to the specification were fully considered and found persuasive and the objections were withdrawn herein.
7. With regard to the rejection of claims 1-9, 11-15 under 35 USC 102(b) as being anticipated by Jones et al., Applicants' arguments and the amendment were fully considered and found persuasive in-part. With regard to the claims 1-7 the rejection is moot since the claims under the rejection were cancelled by the amendment. With regard to the rejection of claims 8-15, Applicants argue that Jones et al. does not teach binding of the target to the sequence specific adapter, that is detected with the help of a second adapter (signal sequence) that is ligated to the second end of the target as required by the

claim 13. The arguments were found unpersuasive. First, the claim 13 as presented do not distinguish first end and second end of the target sequence and the step ii) requires adding a double-stranded polynucleotide signal sequence and a corresponding double stranded adapter, that do not necessarily read on adding the signal sequence to the second end of the target sequence. Second, Jones et al. as discussed in the rejection does teach adding signal sequence and corresponding adapter or probe sequence to one end of the target sequence. Third, as noted in the MPEP 2145 Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), the limitations upon which the arguments were based, not present in the claims. Accordingly the rejection is maintained and rewritten to include the new claim 16.

8. With regard to the rejection of claim 10 under 35 USC 103(a) as being unpatentable over Jones et al. in view of Sorge et al., Applicants' arguments were fully considered and found unpersuasive. As discussed above the amended claim 13 do not recite the limitations upon which the arguments were based. As discussed above Jones et al. does teach the limitations as required by the claim 13 and as discussed in the rejection it is obvious to modify the method of Jones et al. with the method of Sorge et al. Accordingly the rejection is maintained.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

